REMARKS

Applicant notes that Applicant's Response and Amendment filed May 12, 2008 in response to the Final Office Action of February 11, 2008, and all papers accompanying that response, specifically the Statement Under 37 CFR 3.73(b) and the two Terminal Disclaimers were previously entered and are of record. Accordingly, claims 23, 24, 27, 29, 31-34, 37-39, 68, 72, 76, 80, 82, 84 and 95-97 as amended May 12, 2008, are pending. Should the Examiner feel otherwise, the Examiner is respectfully requested to enter the above mentioned response, amendment and accompanying papers.

Entry and consideration is also requested for Applicant's Appeal Brief filed October 29, 2008, and Applicant's Reply Brief filed April 13, 2009. The arguments and case law cited therein apply directly to the rejections and objections in the Final Office Action of February 11, 2008.

Accordingly, all issues raised in the Final Office Action are believed to be addressed.

In addition, this RCE with its accompanying fee and submission serves to withdraw the Applicant's appeal to the Board of Patent Appeals and Interferences from the Final Office Action dated February 11, 2008, final rejection of claims 23, 24, 27, 29, 31-34, 37-39, 68, 72, 76, 80, 82, 84 and 95-97. Notice to the Board will be sent under separate communication.

The following remarks and attached exhibit (Exhibit I) further provide for a proper submission pursuant to 37 C.F.R. § 1.114(a)(1) and consistent with patent office practice per MPEP § 706.07(h).

Applicant submits the following additional remarks and Exhibit I in further support of Applicant's previous arguments of record traversing the Final Office Action rejections that were premised on alleged inherent anticipation of the present claims by the cited publications in which pramlintide was administered to patients having diabetes in order to treat the diabetes by controlling blood sugar. In brief, Exhibit I demonstrates that weight loss was not observed in all

patients who had diabetes, and in many cases were also obese, that were administered pramlintide specifically to treat their diabetes by controlling their blood sugar. Accordingly, a patient treated for control of blood sugar according to the cited art would not have necessarily and inevitably also achieved weight loss.

Exhibit I is a print out of a clinical Study Results web page http://clinicaltrials.gov/ct2/show/results/NCT00467649?show_out=2#outcome3 from the NIH-managed ClinicalTrials.gov website at which U.S. clinical trial results are reported. Exhibit I presents the Study Results of a clinical study entitled "A Study to Characterize Regimens of Basal Insulin Intensified With Either Symlin® or Rapid Acting Insulin in Patients With Type 2 Diabetes." This study was sponsored by Amylin Pharmaceuticals, Inc., the assignee of the present application. The study reports the clinical effects of the amylin analog pramlintide, for which SYMLIN is the brand name, on weight loss in patients with diabetes.

As indicated in Exhibit I, at page 1, pramlintide was administered at 120 micrograms twice a day (i.e. with major meals) to patients with diabetes and who were also taking insulin (Group A). The Examiner's attention is directed to Exhibit I, at pages 3-4, the results section entitled "Secondary Outcomes Measure: Proportion of Patients With no Weight Gain at Week 24." The proportion of patients who did not gain weight (either lost weight or were weight neutral) with pramlintide treatment (i.e., Group A) was 46.4%, which indicates that 53.6% DID gain weight (see page 4 of Exhibit I).

This evidence supports the Applicant's previous arguments and cited case law demonstrating a lack of inherency in the cited art. As noted in the record, to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). The fact that a certain result or characteristic *may* be present in the prior art is not sufficient to establish the inherency—inherency may not be established by probabilities or possibilities. *Continental Can Co. USA, Inc., v. Monsanto Co., 948 F.2d 1264, 1268* (Fed Cir. 1991); *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). Simply stated, it is not sufficient that

a person following the teachings of the cited art sometimes obtains the claimed result—it must invariably happen. Accordingly, Applicant submits that the cited art does not inherently anticipate the claimed methods for the reasons already of record and further in view of the evidence submitted herewith. The specific rejections to which the above evidence and argument is applicable include those of Sections 21 and 22 of the Final Office Action asserting obviousness type double patenting, and Sections 25, 26, 27, 28 and 29 asserting anticipation.

Relevant to the obviousness type double patenting rejections of Sections 21 and 22 that are based on "inherency" alleged to be found in Tsanev (or similar teachings) which is the basis of those arguments, Applicant respectfully further submits that it is well-established precedent that "inherency" has no place in obviousness arguments.

Withdrawal of these rejections is respectfully requested.

In light of the enclosed remarks and the amendments and remarks in the previous submissions, Applicant respectfully requests reconsideration and withdrawal of all objections and rejections set forth in the Final Office Action of February 11, 2008.

Further, Applicants believe all claims presently under consideration to be in a condition for allowance and request issuance of a Notice of Allowance at the Examiner's earliest convenience.

Should the Examiner have any remaining questions regarding the subject invention or its patentability, Applicant encourages the Examiner to contact the undersigned to discuss any issues remaining.

Furthermore, Applicants file herewith an Information Disclosure Statement with references cited in the PTO/SB/08b Form for further consideration by the Examiner.

Fees totaling $810.00 are believed due with this submission. However, if this calculation is incorrect, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Respectfully submitted,
AMYLIN PHARMACEUTICALS, INC.

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